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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence--42 CFR part 8 (OMB No. 0930-0206) and Opioid Treatment Programs (OTPs) - Revision

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. "Certification" is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of

patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form **SMA-162**); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form **SMA-163**); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form **SMA-168**), which may be used by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form **SMA-168** is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11, and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation, and documentation by an OTP of the following: A patient's medical examination when admitted to treatment, a patient's history, a treatment plan, any prenatal support provided to the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered

to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under section 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

A number of changes have been made to the forms. Forms have been reworded for clarification, updated with current SAMHSA mailing and web-submission information, and a few additional fields have been provided for clarity and for providers to best explain their services (e.g., expanding the former global patient census in the SMA-162 to request patient census by drug type—methadone, buprenorphine, naltrexone, or other) and the needs of their patients (e.g., including urinalysis results on the SMA-168 and adding “weather crisis” as a standard option for physician justification of the requested exception). Amendments also include the removal of information pertaining to faxing the forms to SAMHSA, as this is no longer an acceptable form of submission. The burden hours have increased slightly (by 28% or approximately 639 hours) due to an increase in the number of facilities accredited and certified by SAMHSA since the previous submissions of these forms. The forms are available online with a unique feature for both the SMA-162 and SMA-168 that pre-populates certain information within the form. This in turn reduces the program’s time spent filling out the forms as well as the staff time spent on processing it.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

Estimated Annual Reporting Requirement Burden for Accreditation Bodies

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.3(b)(1-11)	Initial approval (SMA-163)	1	1	1	6.00	6.00
8.3(c)	Renewal of approval (SMA-163)	2	1	2	1.00	2.00
8.3(e)	Relinquishment notification	1	1	1	0.50	0.50
8.3(f)(2)	Non-renewal notification to accredited OTPs	1	90	90	0.10	9.00
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs	2	2	4	1.00	4.00
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	10	20	1.00	20.00
8.4(d)(1)	General documents and information to SAMHSA upon request	6	5	30	0.50	15.00
8.4(d)(2)	Accreditation survey to SAMHSA upon request	6	75	450	0.02	9.00
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request	6	6	36	0.20	7.20
8.4(d)(4)	Report of less than full accreditation to SAMHSA	6	5	30	0.50	15.00
8.4(d)(5)	Summaries of Inspections	6	50	300	0.50	150.00
8.4(e)	Notifications of Complaints	12	6	72	0.50	36.00

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs	1	185	185	0.30	55.50
8.6(b)	Submission of 90-day corrective plan to SAMHSA	1	1	1	10.00	10.00
8.6(b)(1)	Notification to accredited OTPs of Probationary Status	1	185	185	0.30	55.50
SUB TOTAL		54		1,407		394.70

Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.11(b)	Renewal of approval (SMA-162)	386	1	386	0.15	57.90
8.11(b)	Relocation of Program (SMA-162)	35	1	35	1.17	40.95
8.11(e)(1)	Application for provisional certification	42	1	42	1.00	42.00
8.11(e)(2)	Application for extension of provisional certification	30	1	30	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA-162)	60	1	60	0.10	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance	1	1	1	1.00	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA-168)	1,325	25	33,125	0.07	2,318.75
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA-162)	10	1	10	0.25	2.50

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance	1	20	20	0.33	6.60
8.24	Contents of Appellant Request for Review of Suspension	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement	2	1	2	5.00	10.00
SUB TOTAL		1,900		33,719		2,507.70
TOTAL		1,954		35,126		2,902.40

Written comments and recommendations concerning the proposed information collection should be sent by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of

comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via e-mail, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, D.C. 20503.

Summer King,
Statistician.

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